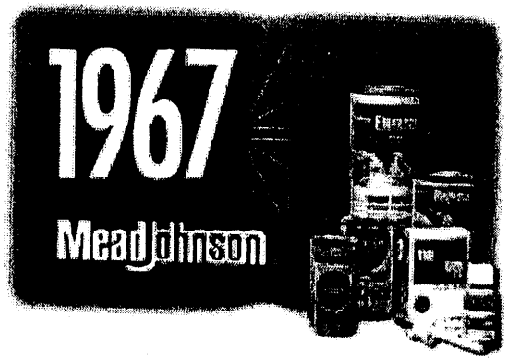

JAMES HANSEN, MD, PhD, FAAP

Director, Medical Affairs

Mead Johnson Nutritionals

MEAD JOHNSON NUTRITIONALS

- Leader in science-based innovation in infant nutrition
  - 1929 SOBEE®
    - First soy protein infant formula
  - 1942 Nutramigen®
    - First protein hydrolysate formula
  - 1966 Enfamil® Premature formula
    - First product for premature infants
  - 2002 Enfamil LIPIL™
    - First US infant formula with DHA and ARA

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OBJECTIVES

- Work with FDA and outside experts to maintain appropriate standards for the development of infant formula
- Ensure that FDA has access to necessary expertise to work collaboratively with industry to design appropriate clinical trials for new infant formulas
- Maintain high scientific standards to ensure protection of vulnerable population

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INFANT FORMULA DEVELOPMENT

- As defined by 21 U.S.C. 321(z)
  - Human milk substitute - by reason of its simulation of human milk
- Goal of innovation for term infant is to produce a product closer to breast milk
  - Qualitative similarity
  - Levels and ratios that optimize nutrition
- Goal of innovation for preterm infant is to adapt nutrition to meet unique requirements

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CLINICAL TRIALS IN INFANT FORMULA DEVELOPMENT

- Reasons to conduct a study
  - New ingredient or new source
  - Safety and efficacy
- Appropriate study design requires input from experts
- The role of growth studies

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GENERALIZATION OF RESULTS FROM CLINICAL STUDIES

- A major reformulation will typically require clinical studies
- Minor changes to a formula supported by well accepted scientific rationale may be possible
- When adding a new ingredient differences between formula matrices must be considered

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GENERALIZATION OF RESULTS FROM CLINICAL STUDIES: PRETERM TO TERM INFANTS

- Important differences exist between term and preterm infants
- Data obtained from preterm infants may not provide a sufficient level of information to assess suitability in term infants
- In certain situations, preterm infants may serve as a model for nutrient availability in term infants

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GENERALIZATION OF RESULTS FROM CLINICAL STUDIES: DIFFERENCE IN FORMULA MATRICES

- Formulas are not identical – even those with the same intended use
- Differences in protein and fat blends between formulas may limit the ability to generalize study results
- Levels and ratios may be important
- Consideration of the matrix must be taken into account as part of the justification for generalization

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GENERALIZATION OF RESULTS FROM CLINICAL STUDIES: DIFFERENCE IN SOURCE INGREDIENTS

- The chemical form of the ingredient is important
- Novel sources of an ingredient may be part of a unique matrix
- The potential exists for interaction between the new ingredient and the matrix of a given formula product

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SUMMARY

- A major reformulation will typically require clinical studies
- Generalization of clinical results to support minor formula changes requires that the source of the nutrients and the formula matrix are adequately considered
- Extrapolation of results from preterm studies to term infants may be appropriate in a limited set of circumstances

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ISSUES TO CONSIDER

- FDA should continue to work with experts from academia and industry to determine the appropriate design of clinical studies

- FDA requirements for clinical data must apply equally to all manufacturers (*i.e.*, the innovator should not be held to a different standard)

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